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Science and Technology

Wide-Area Recovery & Resiliency Program (WARRP)

Medical Countermeasures Response - Anthrax

Assessment of MCM Response Capabilities to an Anthrax Attack and Impact on Recovery

Findings and Recommendations

April 24, 2012



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14. ABSTRACT This summary presentation reviews the approach, findings and recommendations of the Biological Attack Response and Recovery: End-to-End Medical Countermeasure Distribution and Dispensing Processes study. The analysis examines current medical countermeasure (MCM) response capabilities when faced with a large scale biological attack (aerosolized anthrax) and identifies gaps in the MCM distribution and dispensing process. The study recommends cost-effective ways to alter the MCM process and supporting activities to achieve greater efficiency and flexibility and to enable recovery. The study of over 100 process gaps coupled with end to end system analysis revealed that population compliance is one of the most important factors in reaching recovery, an area that is often ignored in response analysis. Twelve overarching deficiency themes were developed and over twenty five possible corrective or preventive actions were identified and assessed against impact on lives saved and expected cost to implement. Nine priority recommendations that have the greatest impact on recovery within resource constraints emerged from this analysis.					
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Overview: Assessment of MCM Response Capabilities to an Anthrax Attack and Impact on Recovery

- **Our Scope:** MCM Response Capabilities Affecting Recovery
- **Methodology:** Cross-functional Team Analyzing End to End Processes, Literature Review (over 200 documents), Expert Interviews (over 30), Gaps (over 100) and Systems Analysis
- **Findings:** Recovery Will Be Hindered By Higher Than Expected Mortality Rates (3x to 5x).
 - Dispersed Federal MCM Leadership, Lack of Uniform MCM Response Architecture, Dependence on Singular Contingency Dispensing Mode, and Undervaluing Population Compliance Are All Major Contributing Factors
 - Reduced Funding And Public Health Staffing Will Amplify Issues – Leveraging External Resources and Multi-Use Solutions Will Become More Critical
 - Planning Does Not Adequately Address Contingencies Like Shelter In Place or MDR Strains or At Risk Populations Including Children, the Elderly, and Infirmed
- **Recommendations:** Identify A Single Lead Federal Agency Clearly Responsible for MCM Preparation and Response Including Architecture, Metrics, and Management
 - Improve Strategic Communications, Address Segmentation of Population, and Develop Alternatives to PODs To Enable Increased Compliance
 - Leverage Other Government Program, Private Sector, Community, and Citizen Resources to Free Public Health Resources To Focus on At Risk Groups
 - Develop and Support Mix of Complimentary Distribution and Dispensing Modes Including Push Models, Closed PODs, Home MedKits, Pharmacies, and Vaccination
 - Incorporate Contingencies Into Planning Activities: The Actions of An Adversary May Necessitate MDR Response, Shelter In Place, Evacuation, Quick Response, or Rationing of Supplies



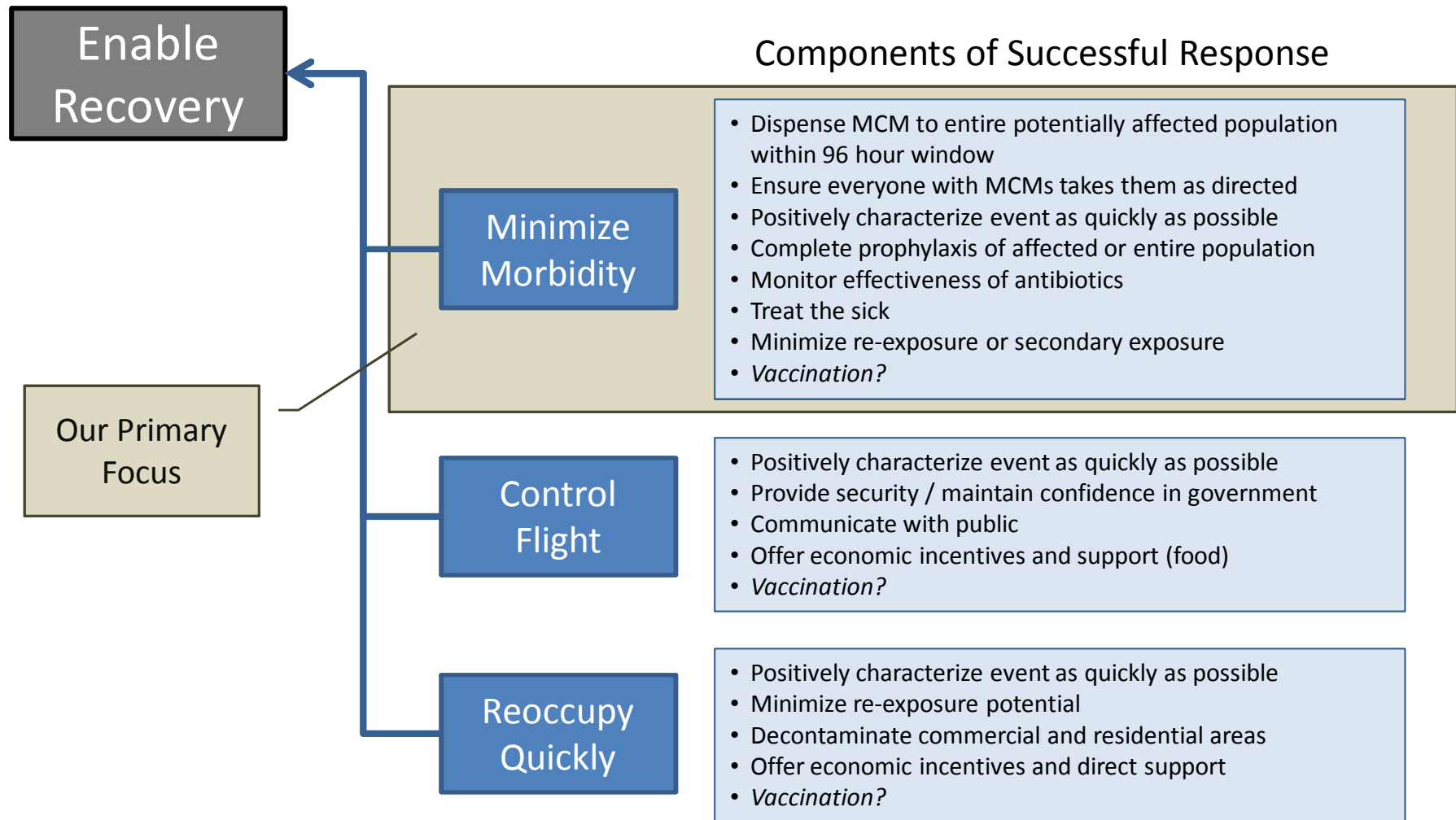
OUR APPROACH



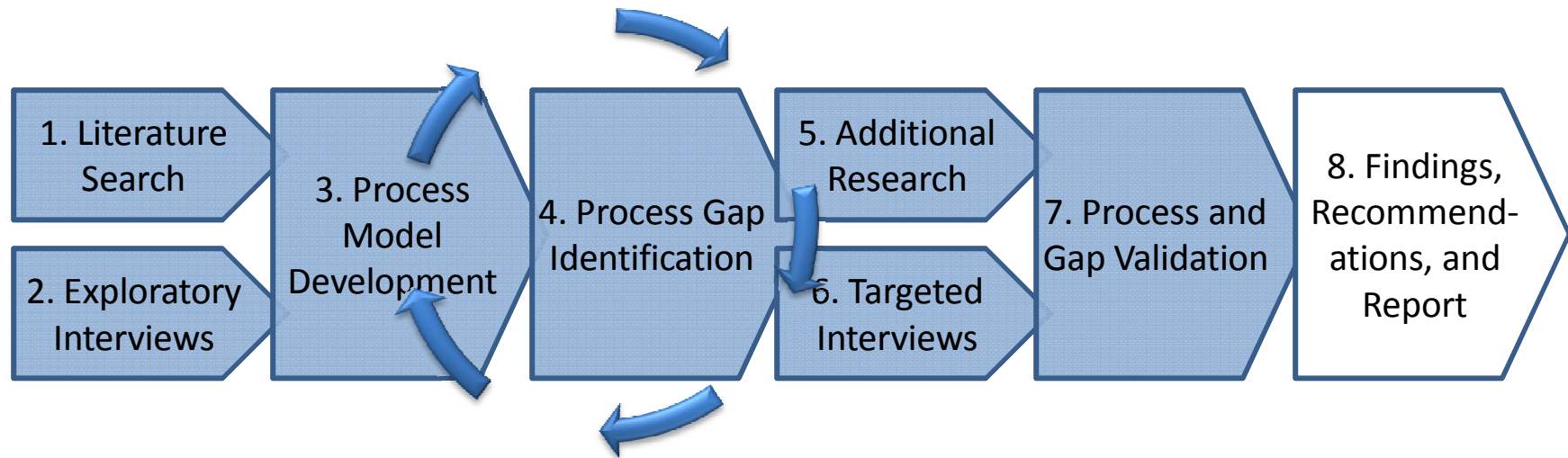
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WARRP MCM and Population Response

Our Scope: Assess end-to-end MCM Response capabilities to determine impact on Recovery and possible improvements



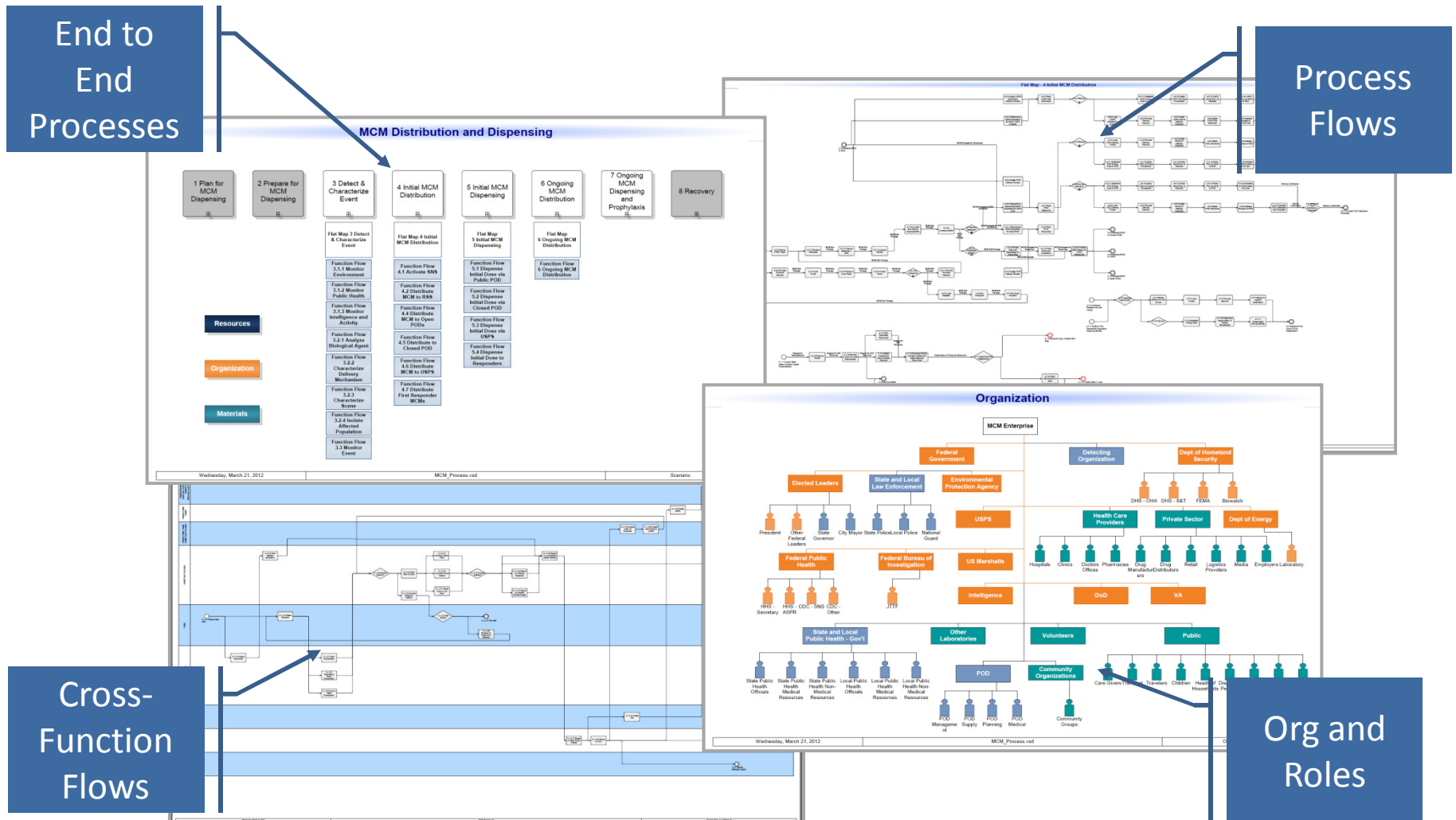
Our Approach: End to End Process and Systems Analysis Yielded Gaps That Were Synthesized Into Findings and Recommendations



- ✓ Over 200 documents reviewed and 35 experts interviewed
- ✓ More than 100 Process Gaps have been identified and analyzed
- ✓ Outcome measures for the end-to-end response/recovery process have been developed
- ✓ 25 specific recommendations have been analyzed for impact, cost to implement, and difficulty to implement
- ✓ A systems analysis of the overall distribution and dispensing framework was completed
- ✓ A report describing Top 9 Recommendations with Appendices was delivered



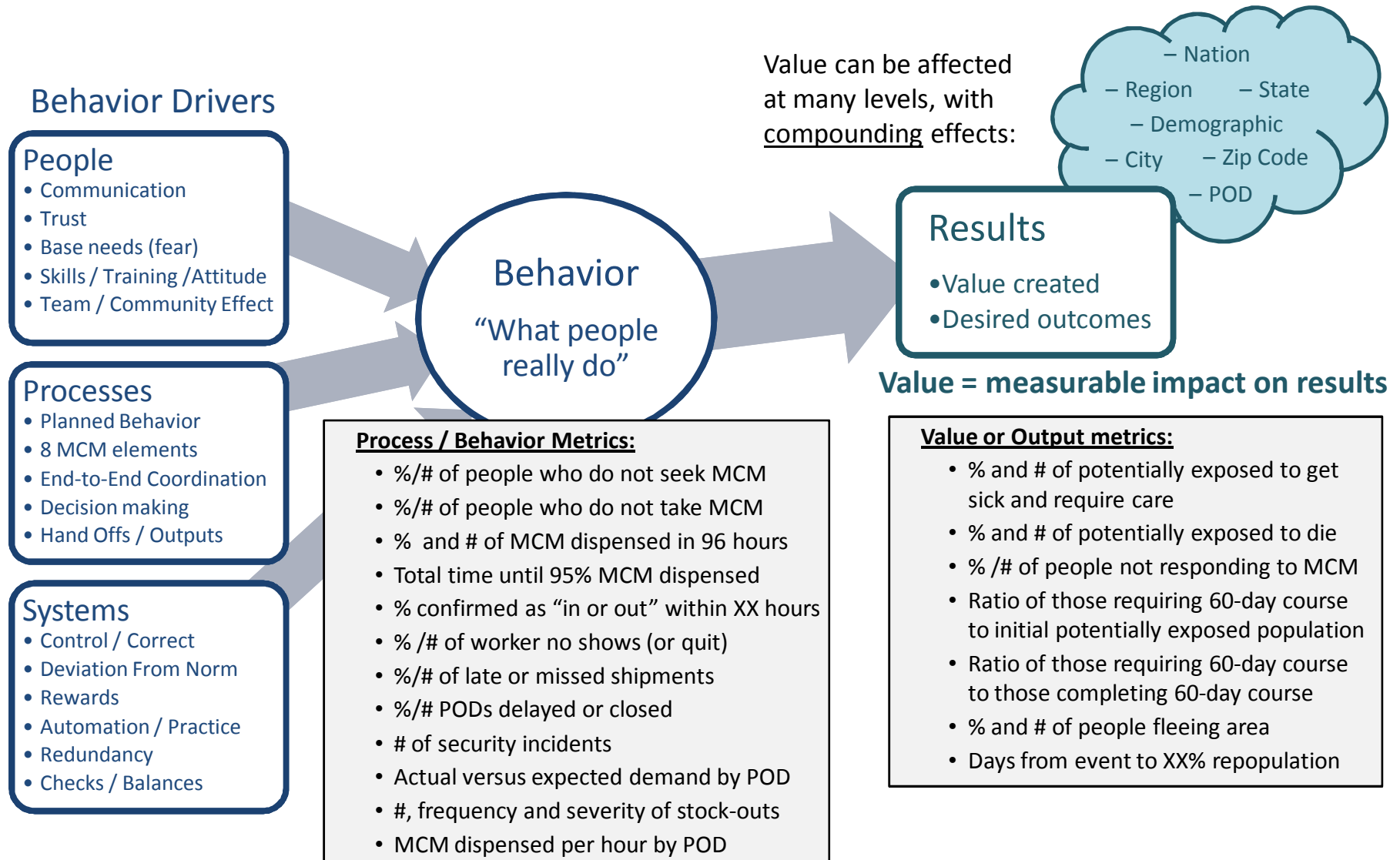
Our Approach: Processes Were Analyzed to Identify Gaps, Unclear Roles, Complexity, and Other Issues



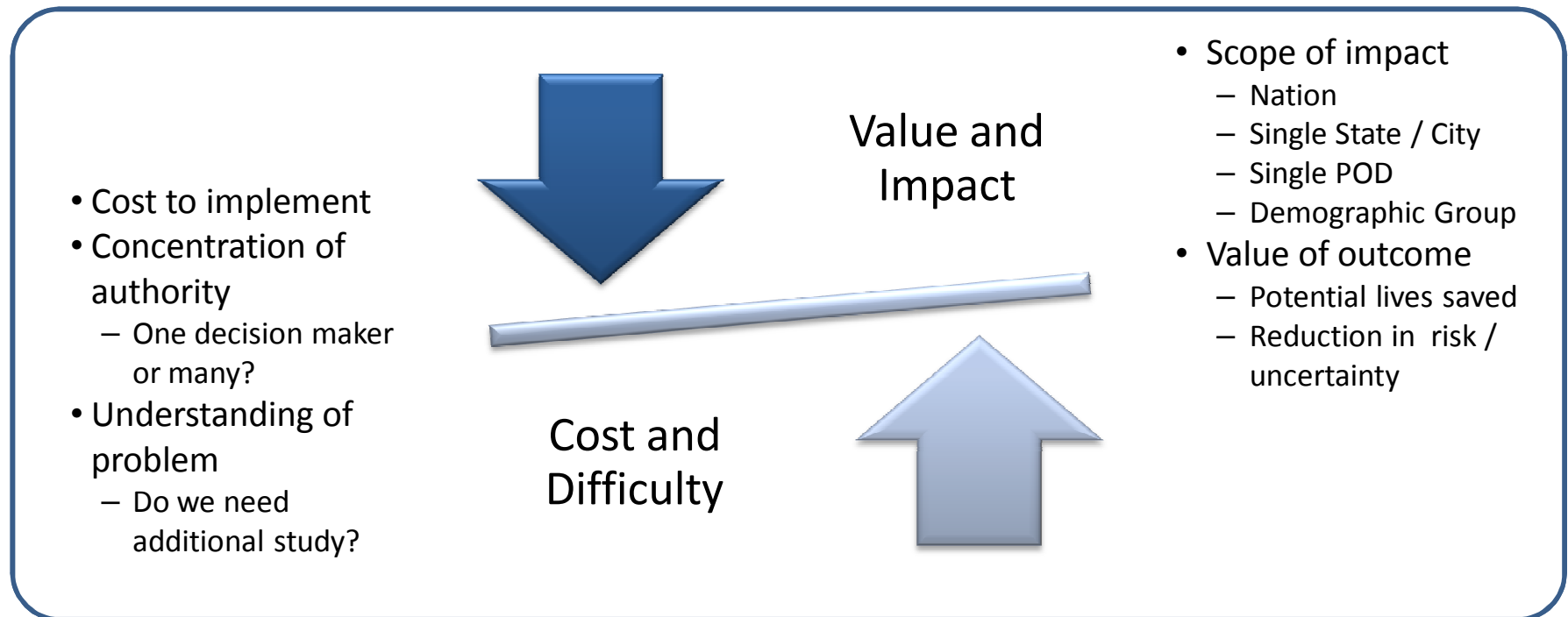
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Our Approach: Interviews and Reviews of After Action Documents Helped Develop Understanding of Actual Behaviors



Our Approach: Cost And Complexity Of Implementation Were Included In Trade Off Analysis to Prioritize Recommendations



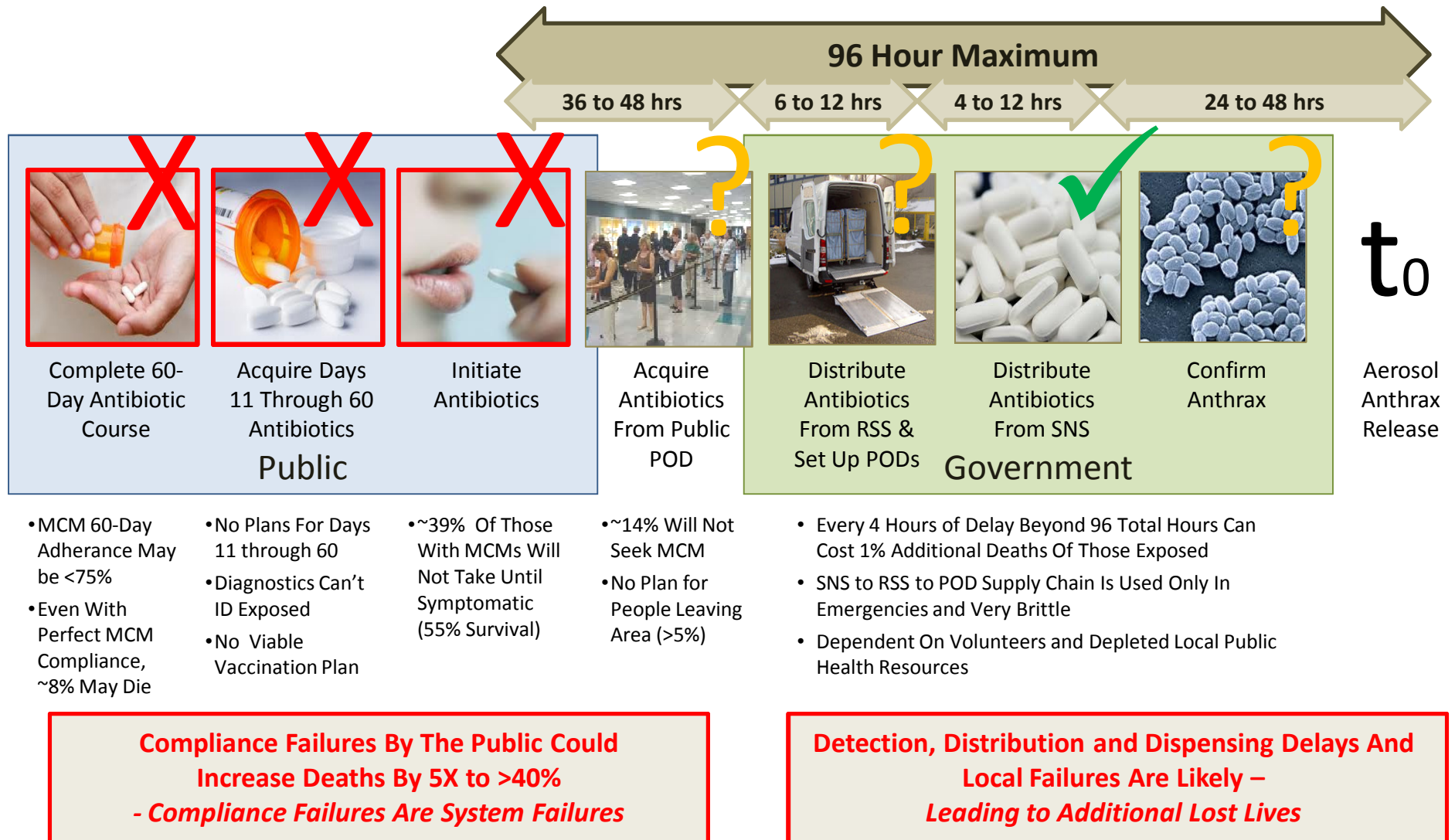
FINDINGS



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WARRP MCM and Population Response

Overlooked Goal: Get First Pills Into People's Mouths In Under 96 Hours and Complete 60-Day Regimen



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WARRP MCM and Population Response

Primary Issue: The Path From POD Activation to Successful Prophylaxis and Treatment Is Not Simple Nor Certain

Once an event is detected, confirmed and characterized –

Near perfect government communication, MCM logistics, and POD operation coupled with perfect public decision making, following of instructions, and adherence to MCM protocols will be required to effect an acceptable outcome – **any failure will be catastrophic**

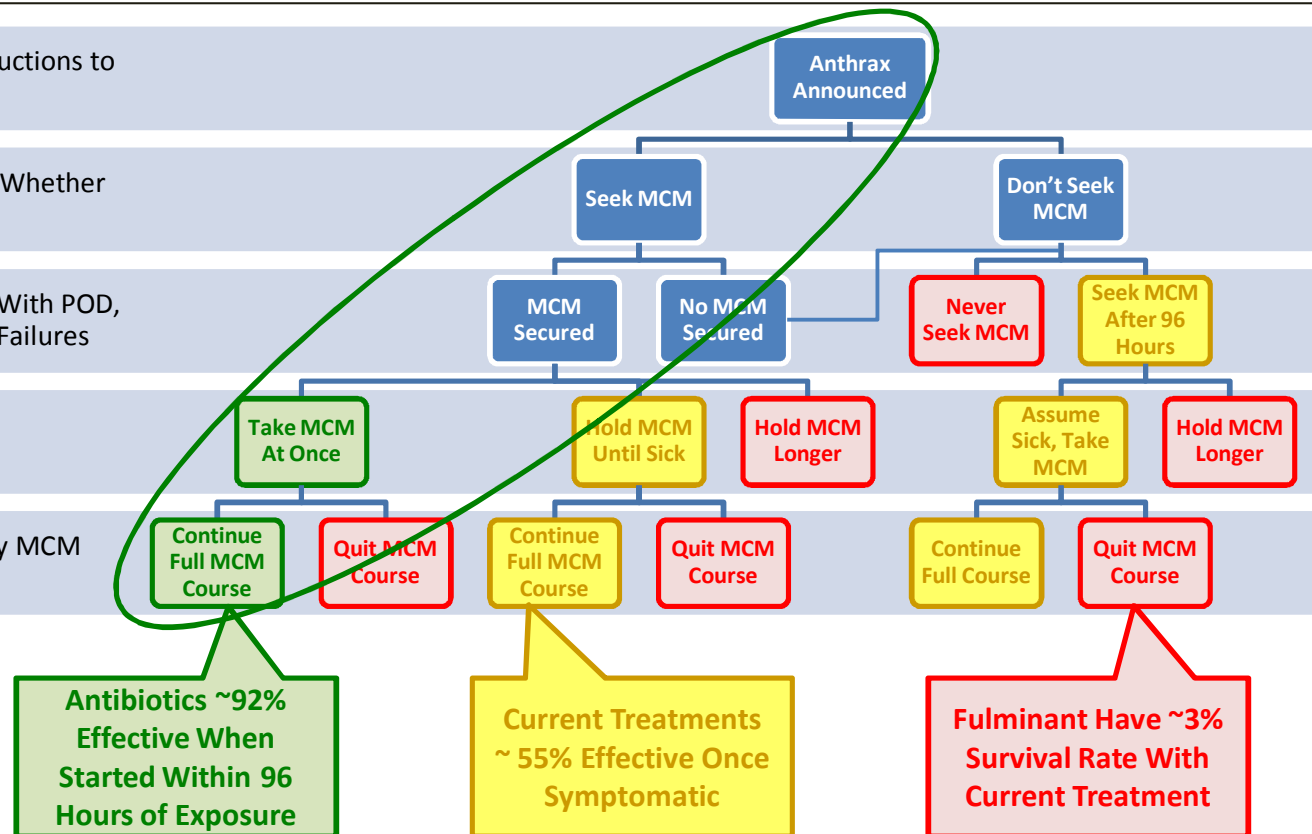
Authorities Issue MCM Instructions to Go to Public POD

Head of Household **Decides** Whether to Follow POD Instruction

Decision to Continue Faced With POD, Supply, Transport, or Other Failures

Decision to Take MCM

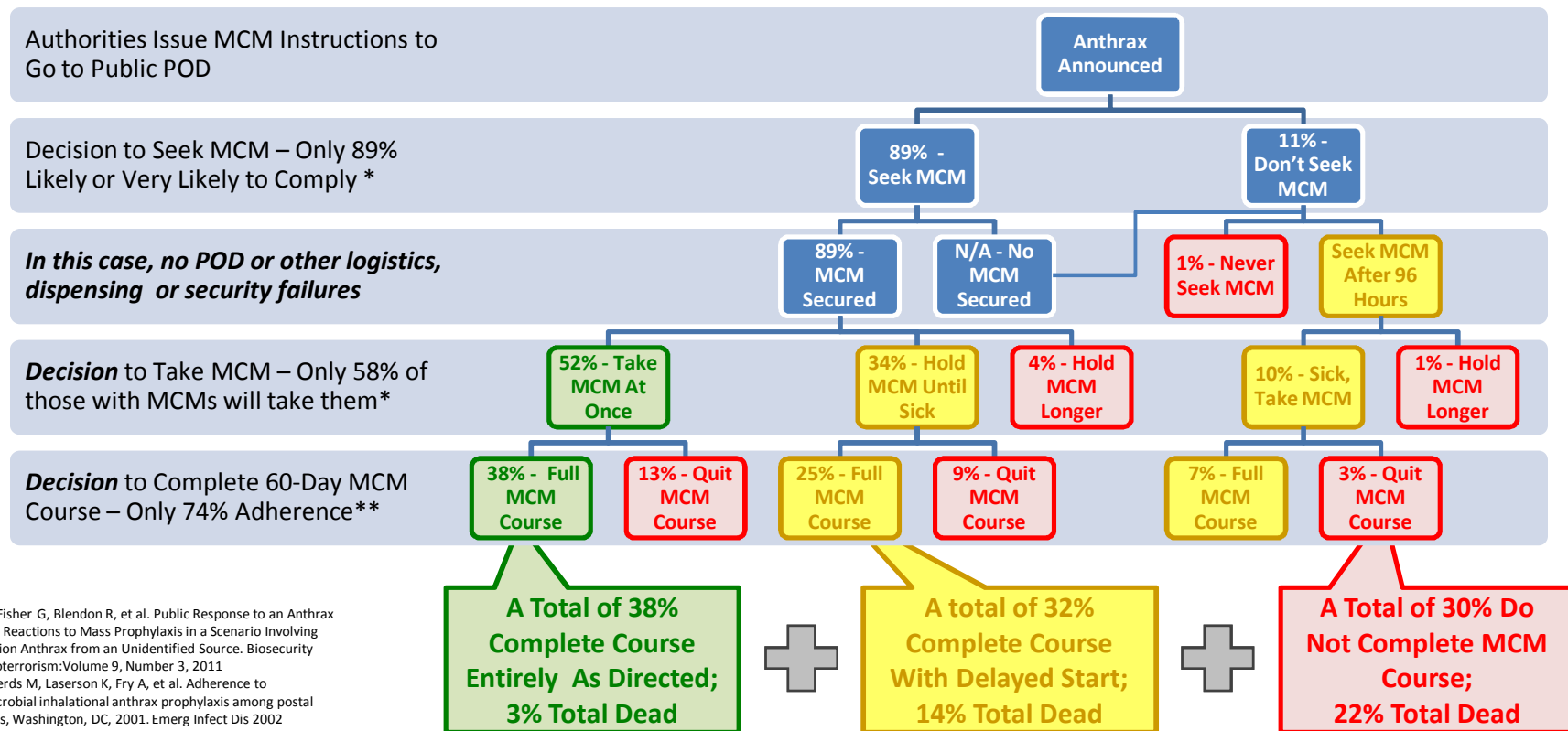
Decision to Complete 60 Day MCM Course



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Human Cost: Even With No POD or Logistics Failures, Public Behavior May Drive Low Compliance and High Death Rates

The result of poor compliance behaviors could be 39% to 48% mortality rates versus 8% with complete MCM Compliance: A penalty of 35,000+ lives in a scenario of 120,000 exposed



* SteelFisher G, Blendon R, et al. Public Response to an Anthrax Attack: Reactions to Mass Prophylaxis in a Scenario Involving Inhalation Anthrax from an Unidentified Source. Biosecurity and Bioterrorism: Volume 9, Number 3, 2011

** Jeffers M, Laserson K, Fry A, et al. Adherence to antimicrobial inhalational anthrax prophylaxis among postal workers, Washington, DC, 2001. Emerg Infect Dis 2002



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Sensitivity Analysis: Public Compliance, Better Treatments and Increased Dispensing Reliability are All Important

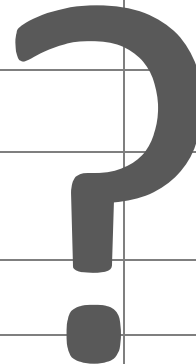
Proforma Analysis of System Sensitivity to POD Failure, Compliance with MCM Instructions (initial and on-going), and Treatment Effectiveness

Scenario	Initial Compliance	Percent Completing	Treatment Effectiveness	Death Rate / Percent POD Effectiveness			
				100%	90%	80%	50%
Perfect Compliance By Public: Best Case	100% Seek and Take MCM	100% Complete 60 Day Course	92% Effective Prophylaxis (All Cases)	8%	12%	16%	29%
Current Compliance	89% Seek and 58% Take MCM	74% Continue 60 Day Course	55% Effective Prodrome, 3% Fulminant	39%	42%	44%	51%
70% Improved Compliance	96% Seek and 87% Take MCM	92% Continue 60 Day Course	55% Effective Prodrome, 3% Fulminant	18%	21%	25%	36%
Increased Treatment Effectiveness	89% Seek and 58% Take MCM	74% Continue 60 Day Course	80% Effective Prodrome, 3% Fulminant	28%	30%	31%	37%
Improved Compliance and Treatment	96% Seek and 87% Take MCM	92 Continue 60 Day Course	80% Effective Prodrome, 3% Fulminant	13%	15%	17%	19%

- POD Failures are most troublesome when compliance is high and treatments are ineffective
- Increasing Compliance by 70% can reduce casualties by as much as 21% - but dispensing must be near 100%
- Increasing the effectiveness of treatment of prodromal cases has significant impact even if compliance and POD effectiveness is low – this an expensive but high impact route
- A combination of improved compliance and improved treatment is most effective

Dispensing Modes: Challenge Is To Offer Right Mix and Not “Best” Solution Based On Contingencies and Local Situations

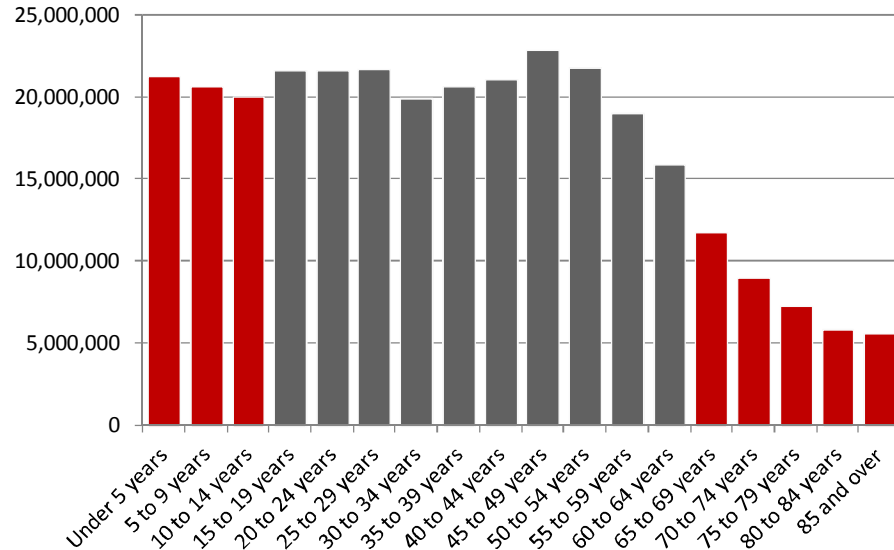
Dispensing Mode	Base Case	Shelter In Place	Evacuation	MDR Strain	Reload	MCM Shortage	At-Risk	TBD
Open PODs								
Closed PODs								
Postal Model								
Pharmacies								
Vaccination (pre-event)								
Vaccination w/ Antibiotics								
Home MedKits								
Local Public Health “Push”								
Mobile PODs								
TBD								



Current System May Not Adequately Address the Needs of All Segments Like the Old, Young, or Infirm - over 1/3 of US

- Complete, effective prophylaxis is complicated by lack of segmentation in planning
- Specific populations with known challenges are not adequately addressed (two examples below)
 - Dosage preparation and monitoring for children is too complex for many
 - The elderly may have acute sensitivity, lack of mobility, and higher rate of drug interactions

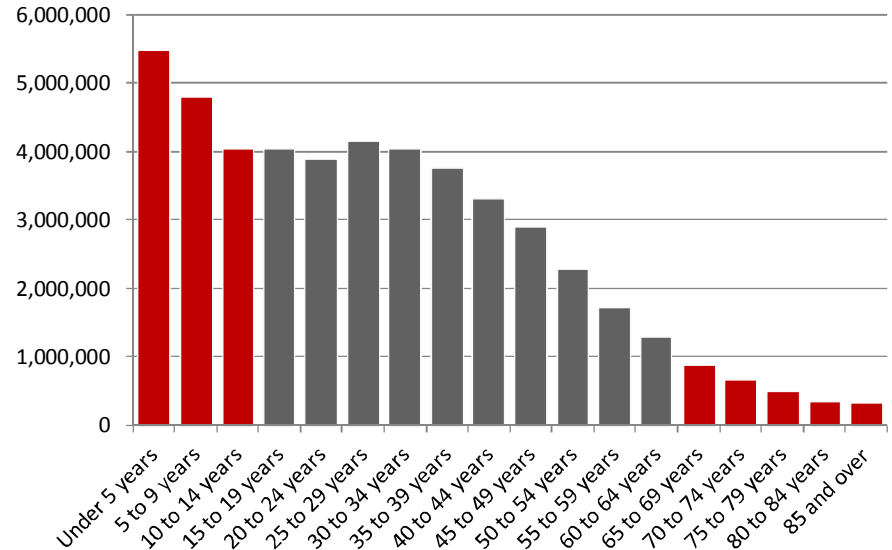
Total 2009 U.S. Population by Age



Percentage of Total Population:

- Children Under 15 Years = 20%
- Seniors Over 65 Years = 13%

Total Hispanic Population by Age



50 Million Hispanics in the US:

- Children Under 15 Years = 29%



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System Analysis Summary: Specific MCM Deficiencies Can Be Addressed Through Coordinated Action

- Make it clear: ***Our Goal is To Get The Pills Into The Mouth In Time and To Continue Taking Until It Is Safe To Stop Treatment***
- Engage the public and create acceptable dispensing options to ***increase initial MCM compliance*** [Predicted: 52%, Target: 100%]
 - People will be more trusting and compliant when offered alternatives managed by trusted parties or by themselves – constant education and innovation required
 - Alternatives like Closed PODs that “preload” the system with information or MedKits that preposition MCM can increase compliance and reduce strain on public POD systems
 - Study and monitor segments and behavior; adjust plans as attitudes change
 - Reduce primary response burden placed on state and local public health officials to allow them to focus on population segments with special requirements
- Improve education, communication and follow up care to ***increase likelihood of completing full MCM course*** [Predicted: <74%, Target: 100%]
- ***Increase reliability of dispensing*** by encouraging the development of alternative channels to PODs less dependent on volunteers, public health resources and unpredictable public behavior in a crisis [Predicted:<<100%; Target: 100%]
- Consider vaccination to enhance treatment, ***enable recovery and address MDR strains***
- Develop and utilize new treatments ***to improve recovery rates and decrease morbidity***, especially of prodromal patients [Predicted: 55% effective; Target: 80+% Effective]



Takeaway: The MCM Value Chain Must Be Viewed As A Single System Designed For Resiliency And Near 100% Coverage

- “Single System” – with single owner, goals and measures

- Only the **end-to-end** result of getting effective countermeasures into the bodies of potentially infected people really matters === **The system includes the behavior of the public**
- Component subsystems must be evaluated for their **contribution to overall system operation**
- Prioritization of investments and performance must be done at the whole system level

- “Resiliency” – leverage proven capabilities and create options

- Resilient systems are designed to correct themselves in the event of an upset – within limits
- MCM response to a biological attack is a series of unusual events with uncertain constraints
- A **comprehensive MCM response architecture** incorporating redundancy, proven capabilities, parallel capacity, continuous measurement and improvement, and flexible inventory is needed

- “100 Percent Coverage” – no luxury of ignoring tough segments or people on the move

- Failure to account for different segments or to cover any portion of the population or likely contingency will result in incremental loss of life and impede recovery === **Only government can fill some gaps – leverage external capacity everywhere else**
- Layering capabilities, shifting decisions and activities to pre-event, incorporating partner assets and capabilities, and engaging the public all help to ensure maximum coverage and reliability
- Complete coverage and resiliency require additional MCM inventories because of overlaps between modes. The cost of additional material may be carried by partners and the public if the government provides stocking options and a greater role in planning and response



RECOMMENDATIONS



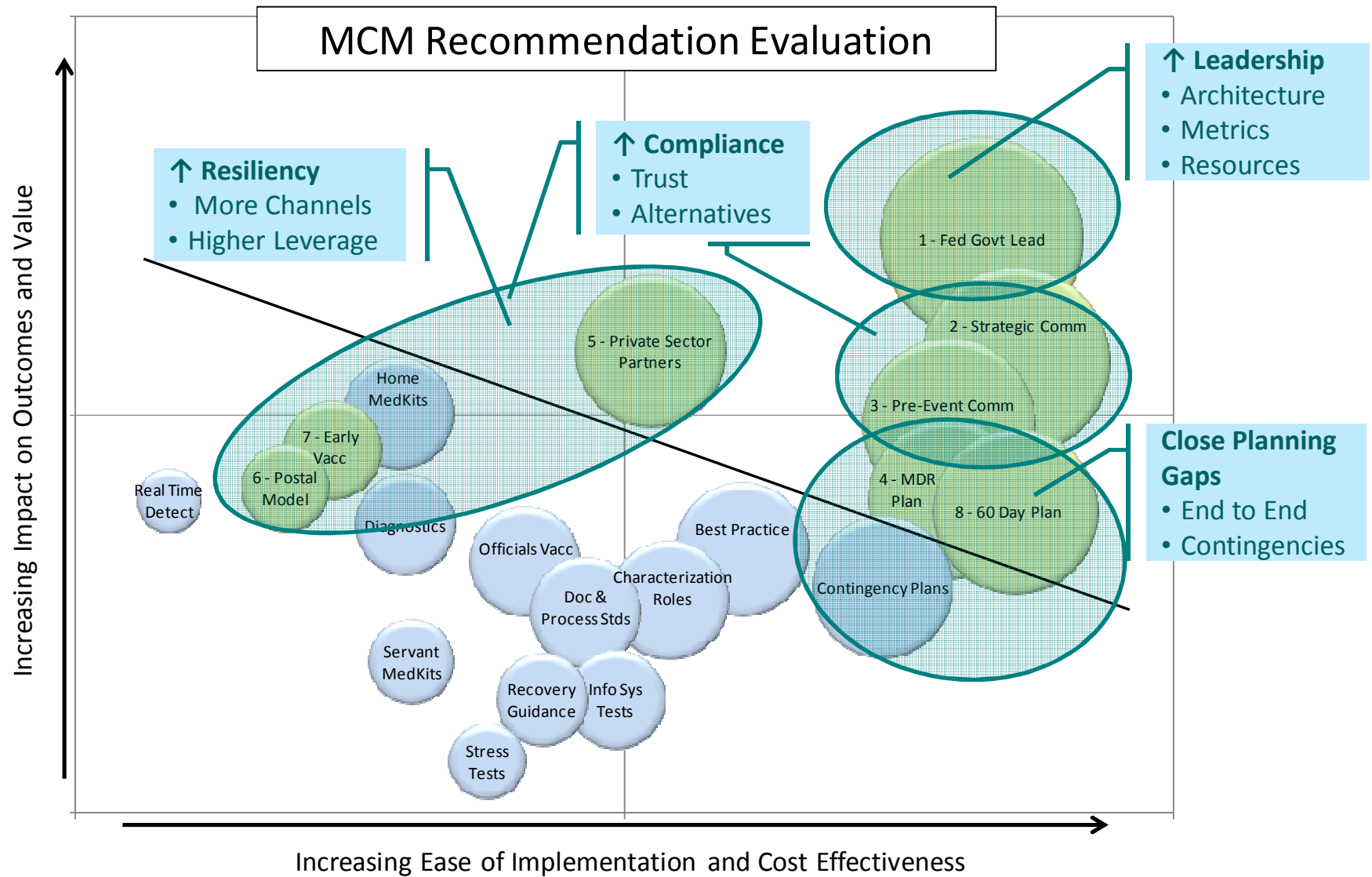
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WARRP MCM and Population Response

Top Recommendations

Recommendation	Description
1. Put the Federal Government in Charge of Bioterrorism Response and Identify a Single Federal Agency to Serve as the Lead	Federal government should take responsibility for coordinating and directing a national response to bioterrorism, including MCM distribution, dispensing and follow on care
2. Improve the Effectiveness of Strategic Risk Communications	Review and refine strategic communications to ensure they are correct, consistent, and constant, and that they are distributed to appropriate communication channels pre-event
3. Provide Pre-Event Communication to Decision Makers and to the Public	Educate decision makers on how to make life and death decisions with incomplete, inaccurate, or non-existent information; and educate the public as to their role in a response and preparation alternatives
4. Use the Federal Government Lead Agency as the One Point of Contact with the Private Sector and Leverage Relationships Nationally	Consider the use of: <ul style="list-style-type: none"> • Pre-developed regional retail prescription databases • Pharmacies as open PODs to supplement public PODs • Tier 1 - Big Box retailers for mass distribution, Tier 2 - Pharmacies for refilling MCMs and serving adjacent communities • Closed PODs in various types of organizations
5. Expand "Push" Dispensing Models for Initial Antibiotic Dispensing	Expand "Push" dispensing model (including postal) to additional cities/regions to provide a quick strike and supplement public PODs, especially if public transport compromised
6. Plan to Vaccinate During the Initial Response Phase with Concurrent Antibiotic Dispensing	Utilize POD model to dispense antibiotics as well as vaccines to affected population during initial response period (vaccination POD and pill POD)
7. Provide Commercial Home MedKit Access to First Responders and the Population	Develop Commercial MedKits for purchase by the general population pre-event to allow for immediate prophylaxis. Begin by providing MedKit to first responders and their families.
8. Develop a Plan for Providing Completion Prophylaxis	Develop standardized plan included roles and responsibilities for obtaining, distributing, and dispensing MCMs to affected population for completion prophylaxis
9. Develop Plan to Address Multi-Drug Resistant Strain Vulnerabilities	Develop standardized, predetermined response plan for an MDR strain

Top Recommendations: Intended to Increase Compliance and Resiliency While Closing Planning Gaps At Lowest Cost



BACK UP SLIDES



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WARRP MCM and Population Response

Additional Recommendations (not in priority order)

Recommendation	Description
Develop Real-Time Pre-Symptomatic Diagnostic Capabilities	Invest in development of technologies capable of determining affected population/infected individuals
Provide Volunteers/Public Servants and Their Families with Pre-Event Vaccination	Reduce time to respond and dispense by ensuring volunteers/ public servants (and their families) receive vaccination before attack and can immediately respond
Develop Flexibility and/or Contingencies to Current Plans	Develop contingency plans to account for unplanned population behavior, delayed timelines, and failure of task execution
Increase Sharing of MCM Distribution and Dispensing Best Practices Between States	Create additional forums for discussion of common problems and possible solutions for MCM distribution and dispensing as well as to promote general coordination around response processes
Initiate Exercises to Test/Stress Plans	Plan and conduct exercises to test pre-existing plans under simulated bioterrorism conditions to better train state/local government and responders and identify areas requiring additional resources or contingency plans
Provide Access to Commercial Home Med Kits to the Population	Develop commercial Med Kits for purchase by the general population pre-event to allow for immediate prophylaxis

Additional Recommendations (*cont'd*)

Recommendation	Description
Develop Better Definition of Roles, Responsibilities, and Expectations Around Characterization	Delineate roles and responsibilities for entities involved in agent/event characterization and set appropriate expectations around characterization timelines so they may be incorporated in response plans
Create Federal Guidance / Training for Recovery Processes	Develop and provide standardized guidance and training around roles, responsibilities, expectations and tasks involved in recovery process to federal, state, and local stakeholders
Develop Real-Time Biological Agent Detection Capabilities	Invest in real-time biological agent detection technologies, particularly environmental
Test Ability of Medical Information Systems	Conduct test of medical information systems (e.g. HAN) to keep pace with rapidly developing scenario
Develop Uniform Documentation and Standardization of Dispensing Procedures	Create guidance on best-practice dispensing procedures to allow for quick, standardized decision making, particularly around a regional response



DETAILED FINDINGS



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WARRP MCM and Population Response

Findings: Themes and Interview Results

1. No clear answer to “who’s in charge?”

- No clarity as to federal vs. local problem
- No clarity as to roles and responsibilities among federal agencies

Interview quotes:

- “There is an issue relating to ownership: the ‘who’s in charge’ question. This flows into all levels of government (local, state, and federal). This issue would be magnified by the magnitude of the incident we’re talking about.”
- “The number one gap in the process is the perceived disconnect among federal agencies. Locals have trouble understanding and differentiating between federal agency roles, responsibilities, and authorities. Who really is the lead? Who is in charge during what scenario, and what do they bring to the table?”
- “Locals struggle with understanding the roles and responsibilities during an emergency response. Who’s in charge? What are the legal issues?”

2. High-consequence decision making for a biological attack has not been exercised, and the inability or delay in making these decisions may stall or stop the response process

- Decision makers may be forced to make a decision with inaccurate, incomplete, or non-existent information

Interview quotes:

- “There is no standardization of plans between feds, states, and locals as far as decision-making during an event.”
- “One of the biggest gaps is looking at a continuum, or looking at the end-to-end process. We are deficient on socializing crisis decision making to leaders – the same leaders that need to be driving critical preparedness steps.”
- “We have not thought enough about the level of consequence of delayed decision making.”
- “We need leaders who are willing to make hard decisions. The best laid plans are going to be futile without this.”

Findings: Themes and Interview Results

3. State and local plans are developed independently without clear directives, and there is no overarching coordination for response plan execution

- No acceptable venue for sharing information or best practices
- All federal help comes in the form of recommended guidance, which states and locals can choose to accept, or not

Interview quotes:

- “The lack of a standardized approach [among states and localities] greatly complicated the management of pharmacy activities [during H1N1].”
- “Each county and state had different reporting requirements. For future events, the process needs to be more directive than consultative. Tell them how to do it. Provide directives rather than recommendations. In the absence of clear guidance, states and counties did what they wanted to do, resulting in inefficient and ineffective processes.”
- “The CDC allows each state to make its own decisions. CDC simply provides the drugs. Some states took the lead [in H1N1 response], while others pushed responsibilities down to the counties. The lack of consistency among states was a big problem.”
- “It would help if the process was more directive instead of consultative. The federal government simply provided recommendations [during H1N1]; states and counties decided whether or not to take them.”
- “Whatever process is designed should be consistent across states. The concept of ‘home rule’ makes this exceedingly difficult, since even counties and underlying municipalities often have divergent processes for emergency response.”
- “There is little control of the [MCM] inventory once the CDC transfers the material to the states. The resources cannot be redistributed [to other states] once they are pushed out.”
- “Across the country, there are heterogeneous operational capabilities. We need to implement the same process across the entire U.S., in all jurisdictions.”
- “Need to look at responses regionally or nationally instead of as a local event only.”
- One city was “totally unaware of the progress that had been made by the CDC, and assumed that nothing had been done. Federal planners operate behind a veil. They would like if the CDC kept the field planners apprised of progress that had been made or updates.”

Findings: Themes and Interview Results

4. A local public health approach does not appreciate the urgency of the situation or the intent of a thinking adversary

- Scientists and PH officials rely on constant data collection and evidence to make high-consequence decisions

Interview quotes:

- “From the FBI perspective, a bioattack is an attack [on the nation], not a public health emergency. It would be a federal issue, and the federal government would be in charge.”
- “A biological attack would quickly be raised to an Incident of National Significance. All levels of government would be involved, as this would be an attack on the nation. It would not be confined to a local event.”
- “Many people do not see this as an attack on the nation, but see it as a public health emergency, which means we are very limited in response strategies. We will rely on public health officials for response rather than a federal defense response.”
- “Public health officials think, ‘What if I’m wrong?’ They do not like to pull the trigger [on response] without a level of certainty.”

5. No planning has been done around post-48 hour response and recovery

- There are no definitive plans for administering completion prophylaxis
- “Recovery” has not been defined, so planners do not know how to achieve that outcome

Interview quotes:

- “The follow-on dispensing plan is wide open. Locales may use PODs, they may use pharmacies...who knows?”
- “The biggest issue with recovery is how little attention has been given to it.”
- “One huge gap is planning for days 11-60. Many groups have made great strides in planning for days 1-10. [There are no] finalized plans for days 11-60. Those days will require a lot of federal input and assistance.”
- “The issues of recovery are not really being discussed.”
- One interviewee “guess[ed] that the information and/or plans at the federal, state, or local level will not be clear-cut on how to deal with the post-48 hour response.”

Findings: Themes and Interview Results

6. Clear and consistent communications from a trusted source will ultimately affect public confidence and compliance

- Very few stakeholders have pre-scripted communications
- No clear overarching communications guidance from any entity

Interview quotes:

- “Mass prophylaxis stalls if there isn’t a cooperative citizen, and their cooperation depends primarily on the message that is communicated.”
- “Another gap is accurate and timely communications. There must be consistency and clarity of messaging. We will need clear, easily accessible, multiple-platform messaging.”
- “Good public messaging will be necessary for any response mechanism to work.”
- “Credible, well-prepared and anticipatory messaging will be key. It is important to get media on the side of the government right out of the gate. The messaging needs to be consistent in order for the public to cooperate.”
- “A huge challenge is communications to the public. Planning in this area is inadequate at best. What kind of behaviors is an event with 24/7 news likely to bring to bear? Plans do not take into account the psychological or sociological reaction of people.”

7. No serious consideration has been given to alternate scenarios (e.g. MDR strains, reload)

- All planning is done for one city scenarios with treatable strains

Interview quotes:

- “Reload is not as much of a part of the conversation as it should be. It is a real concern for bio.”
- One interviewee “has never seen a federal plan for MDR anthrax.” They suggest “that they would tweak the existing response plan as events unfold to combat MDR. There have been discussions at the HHS level to determine what the operations would be in this case, but nothing has been decided.”
- One planner “hasn’t really focused on planning for a double strike or multi-city attack. The Unified Command would more resources as best as they can to address two problems. A double strike and/or antibiotic resistance would cause a real problem.”

Findings: Themes and Interview Results

8. No clear and consistent national plan for leveraging the private sector for distribution and dispensing

- Any agreements with the private sector are done on an ad hoc basis by individual states and localities

Interview quotes:

- “Katrina was the benchmark disaster for realizing that the private sector could get supplies through a lot quicker [than government] and without the red tape.”
- “The government shouldn’t create their own or new systems [for response]. The public and private sectors have to trust each other in this process.”
- One state “has been putting a lot of pressure on BARDA, SNS, HHS to establish agreements with big pharmacies on the federal level. There has been some success working on the regional level, but there has not been much progress on a national level.”

9. In a multi-city attack, there may be inadequate amount of product available nationwide in both the SNS and the private sector supply chain

- For these ubiquitous antibiotics, the private sector relies on a just-in-time system due to the predictability of demand; these products are not stockpiled within hospitals or pharmacies

Interview quotes:

- “There is a concern that there is not a sufficient amount of material in the SNS or in the commercial market [to respond to an attack].”
- “In the event of an anthrax emergency, there may not be enough retail supply to meet demand. Inventory is just-in-time. They do not maintain huge buffers in stores.”
- “In planning SNS assets, they found that a three major city scenario would have taxed the SNS, and the five city scenario would bring it to its knees.”
- “One of the biggest gaps is do we have enough quantity of product to provide to the public in the case of a large-scale attack?”

Findings: Themes and Interview Results

10. An adequate workforce for both planning and response is a major issue because of the decrease in Departments of Health staffing and heavy reliance on volunteers

- Locals may not have enough resources to respond to an attack of this magnitude on their own

Interview quotes:

- “In training exercises, the maximum number of PODs set up at one time is about ten. There are not enough volunteers to stress the PODs, so we don’t know what it’s really going to feel like when an emergency hits.”
- “There is no continuity of personnel across public health in emergency planning. Public health departments are suffering from brain drain.”
- “For planning purposes, the assumption is that 60% of volunteers will show up to work PODs. Jurisdictions need to learn how to optimize PODs with non-optimal staff levels.”
- In working on the preparedness and response issues for several years, one interviewee’s main worry is “not having enough staff”.
- “Manpower is the biggest weakness of PODs. Estimated needs are huge. The majority would have to come from volunteers. In an emergency, they expect only 1/10 of volunteers to show up. They likely won’t be able to open up all of the PODs.”



Findings: Themes and Interview Results

11. Funding cuts will cripple the ability to plan for or respond to an attack

- Public health funding is being cut at all levels, and preparedness is one of the lowest priorities among state and local Departments of Health
- Funding cuts are prevalent across the board in the federal government

Interview quotes:

- “Public Health Awareness Cooperative Agreement Funding is eroding. This will make it difficult to address preparedness gaps at any level.”
- “The impact of budget cuts has been huge on local health departments, especially in the areas of planning and response. They will probably not have an adequate workforce to carry out the response in most cities because of these cuts.”
- “State and local public health departments are on the verge of shutting down due to a lack of funding. If labs don’t have funding, they don’t have the capacity to diagnose these diseases. Public health infrastructure is key. Public health is a lynch pin in making sure these response and recovery processes occur.”

12. There are no clear goals and objectives for response to a bioattack, including MCM distribution and dispensing

- Planning has not been done with the end goal in mind
- Reasonable and practical metrics have not been established to measure the effectiveness of this process

Interview quotes:

- “The CRI objective is to get antibiotics to the target population within 48 hours, but it does not clarify what the target population is.”
- “The overarching problem is that the [biodefense] community has not agreed on what the goals and objectives of our biodefense efforts are.”
- “The dispensing of MCMs itself does not predict success. The responsibility of the federal government goes beyond administering the product. People at all levels think the systems to determine if the MCMs are being taken or if they are effective are coming from someplace else. No one is claiming responsibility for these metrics.”

DETAILED APPROACH



**Homeland
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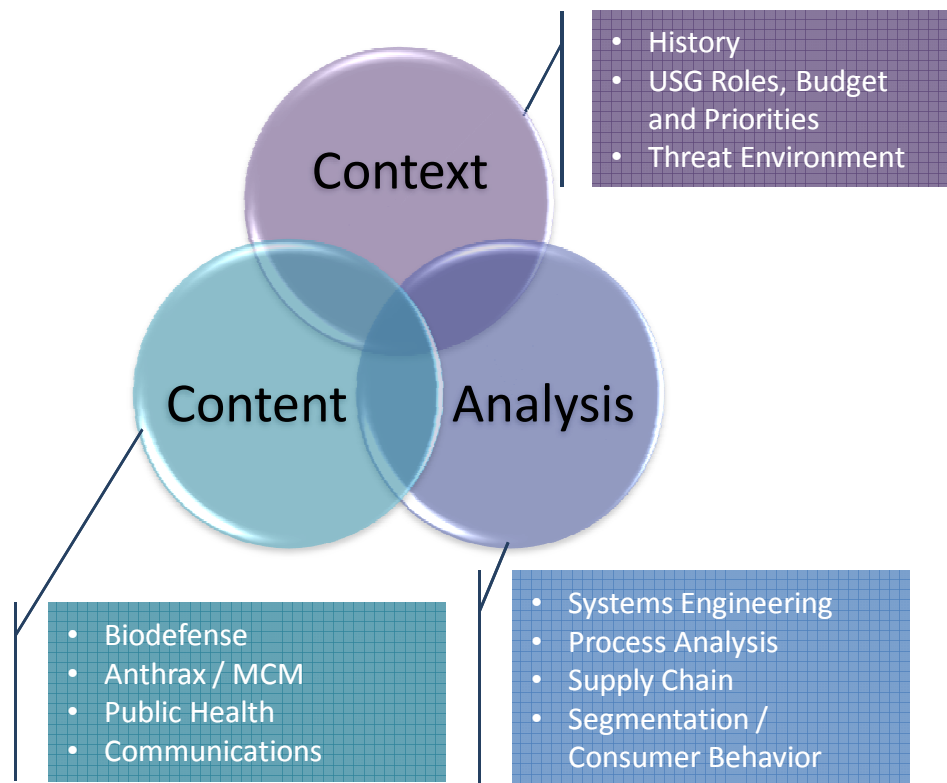
WARRP MCM and Population Response

Our Team: Cross-functional mix of experienced policy, technical and consulting professionals

A Blend of Skills is Required to Assess MCM Issues and Solutions



Our Seasoned Team Covers All Needed Areas



- **Dr. Robert Kadlec** – former White House and Senate biodefense advisor, career military
- **Mr. Michael Chervenik** – 8 years biodefense, 25 years engineering and strategy experience
- **Ms. Sheana Cavitt** - 5 years experience in MCM distribution, intel and public health
- **Mr. Jeff Hokenson** – 15 years experience in market segmentation and communications
- **Dr. Chan Harjivan** – pharmacologist, 15 years executive consulting experience
- **Mr. Tom Green** – 20 years military and supply chain analysis experience
- **Ms. Shabana Farooqi** – 5 years biodefense consulting experience
- **Ms. Lauren Oby** – 3 years process mapping and analysis experience

Approach: Over 35 Targeted Experts Interviewed - Mix of Federal, State, Local, and Private Sector

Name	Organization
Richard Danzig	SME
Carter Mecher	VA
Ken Rapuano	MITRE
Sid Baccam	IEM
Nathaniel Hupert	Cornell Medical School
Lisa Koonin	CDC/OID/OD
Eva Lee	Georgia Tech
COL Bob Mauskopf	VA DOH
Matthew Feltman	Kroger/Giant
Michael Robbins	Chicago DOH
Isaac Weisfuse	NYC DOH
Jack Cantlin	Walgreens
John Kavanagh	PwC, Former FBI
Cyndi Lake	Alexandria VA DOH
Gerry Epstein	DHS
Ted Brown	KETCH Consulting
George Korch	HHS

Name	Organization
Greg Burel	Director, DSNS/CDC
Mike Rackley	Target
Bill Raub	SME
Jack Herrmann	NACCHO
Nicki Pesik, Tracee Treadwell	Anthrax Management Team, CDC
Jude Plessas	USPS
David Starr	NYC DOH
Bob Hooks	DHS OHA
Matthew Minson	SNS Houston
James Blumenstock, Gerrit Bakker	ASTHO
Cathy Polley, Rhett Asher	FMI
Alex Adams	NACDS
Parney Albright	Lawrence Livermore
Stephanie Dulin	CDC
Rear Adm Ali Khan	HHS

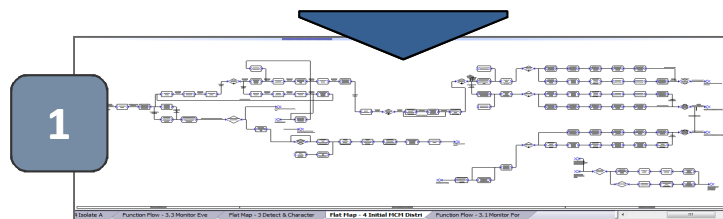
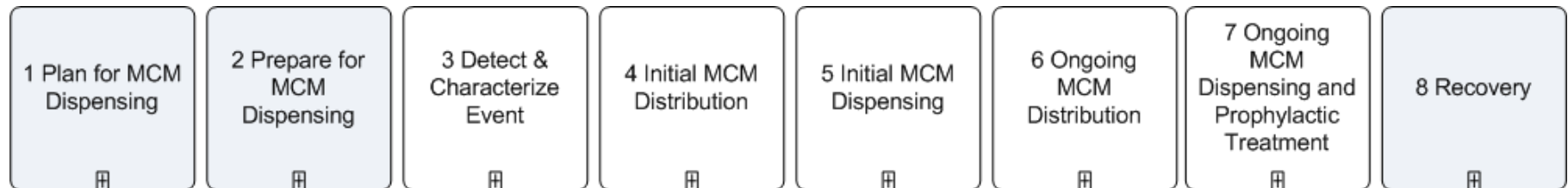
Approach: Over 200 Articles, Texts, Studies and Other Documents Were Reviewed

- Each document is accessible to team via searchable project site
- Interview notes linked to schedule system and also fully searchable
- Written directory to documents also maintained (list available)

The screenshot displays a web application interface for the 'WARRP Medical Countermeasures Response' project, specifically the 'Files' section. The top navigation bar includes links for 'Back to Dashboard', 'Switch to a different project', 'Project Settings', 'My info', 'Sign out', and a 'HELP' button. Below the navigation, the project name 'WARRP Medical Countermeasures Response' is followed by the user 'Stokes Evans'. The interface features a tabbed menu with 'Overview', 'Messages', 'To-Dos', 'Calendar', 'Writeboards', and 'Files' (which is active). On the right, there are buttons for 'People & Permissions', 'Search', and a printer icon. The main content area shows a list of files under the heading 'Files in: Background - Psych and Behavior'. The list includes several PDF documents, each with a title, author, date, and file size, along with a link to 'Upload a new version'. The right sidebar contains a 'List view' button, an 'Upload a file' button, and a 'File storage space' section indicating 9% usage of a 5 GB limit. Below this, there are 'Sort by' options (Date and time, A-Z, File size) and a 'Categories' section with a list of links to various background documents, including 'Background - Psych and Behavior' which is highlighted.

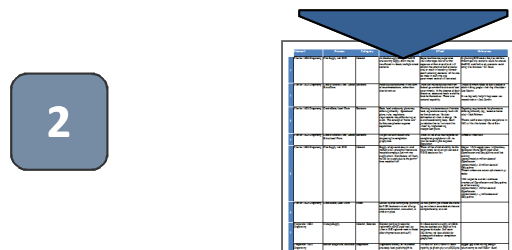


Approach: Our end-to-end process model helped us identify and organize over 100 potential gaps

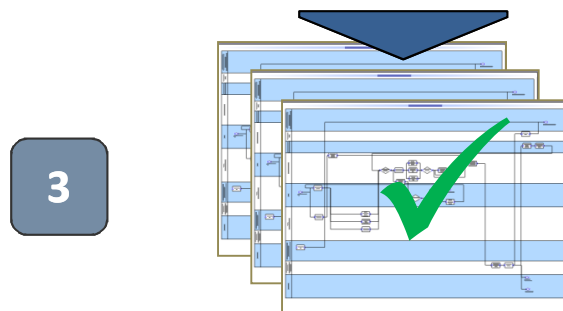


Built detailed process flow diagrams for primary processes supporting elements 3, 4, 5, 6, 7

Process Model: “80% Solution” completed in Microsoft Visio Tool and available for deeper analysis



Gaps were identified through modeling



Gaps were validated through interviews and research

Gaps: potential areas of process failure or contributors to failure elsewhere in the response or recovery phases

- Anything that reduced likelihood that public will comply with directions to acquire or take MCM / antibiotics
- Anything that delayed initial dispensing
 - Decision making – Logistics - Process coordination-Communication
- Anything that decreased the likelihood of a 100% response
 - Use of contingency systems versus existing systems
 - Departures from normal processes
 - Reliance on the public
 - Lack of redundancy
- Anything that decreased confidence in government



Homeland Security

Approach: Effectiveness and Activity Metrics Were Developed to Assess Impact of Gaps and Recommendations

LOGISTICS – Measure against plan:

- % /# of worker no shows (or quit)
- %/# of late or missed shipments
- %/# PODs delayed or closed
- # of security incidents
- Actual vs expected demand by POD
- Communication success rate
- #, frequency and severity of stock-outs
- MCM dispensed per hour by POD
- Response and shipping time from SNS

CHARACTERIZATION – Measure:

- % confirmed as exposed or not before becoming symptomatic - Diagnostics
- %/# of people not responding to MCM – MDR
- Elapsed time from event to detect

COMPLIANCE – Maximize:

- %/# of those requiring 60-day course to those completing 60-day course
- %/# of people who take MCM immediately
- %/# of people who seek MCM immediately

DISPENSING – Maximize:

- %/# of MCM dispensed in 96 hours
- %/# of MCM dispensed in 96 + XX hours

OUTCOMES – Minimize:

- %/# of potentially exposed to die
- %/# to get sick and require care
- %/# of people fleeing area
- Days from event to XX% repopulation

Potential Impact of Recommendation:

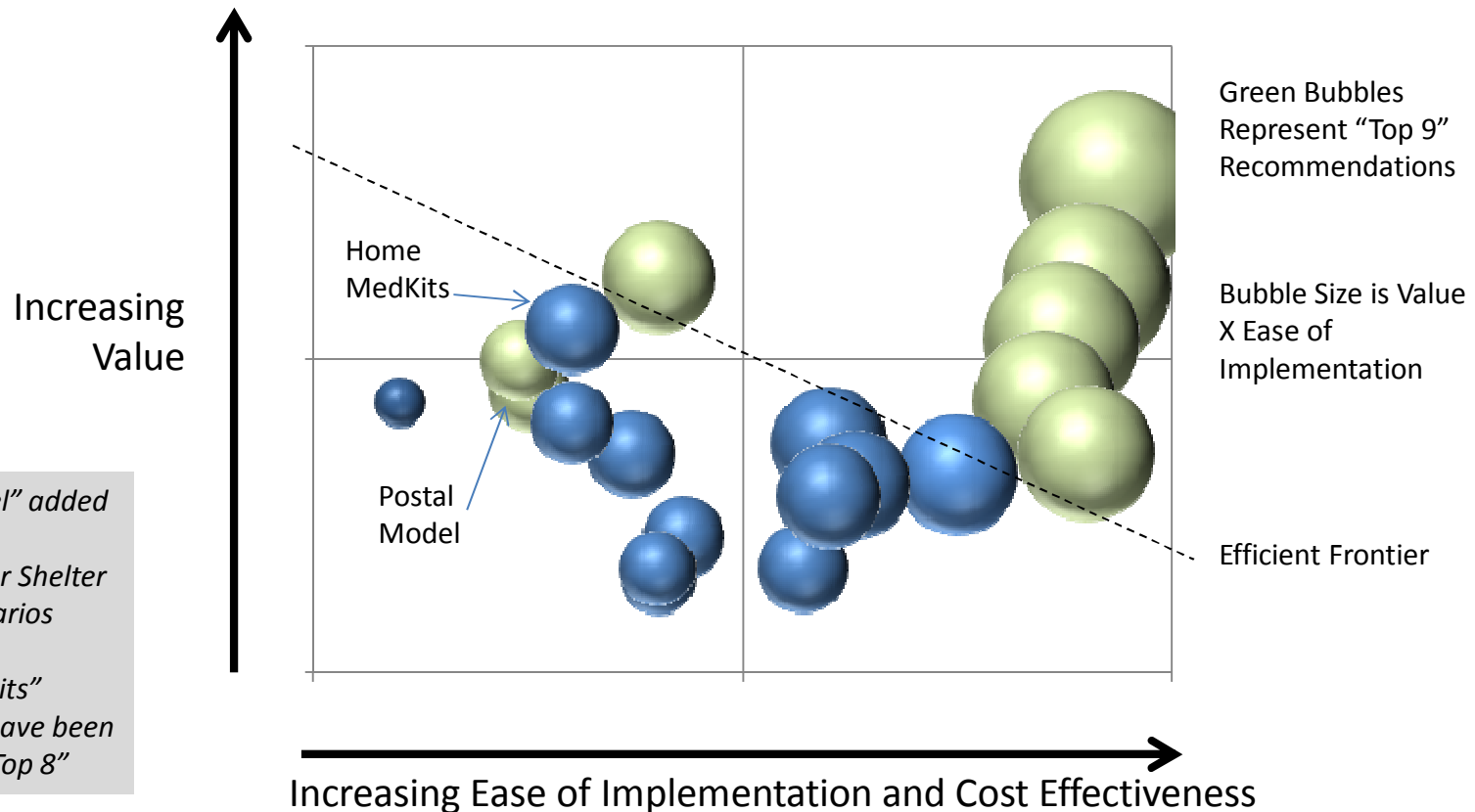
- National
- Region / State
- County / City
- Neighborhood / Zip Code
- Demographic



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The “Top 9”: Recommendations Were Selected Based on Strategic Requirements Including Cost - Not an Exact Exercise

Plot of Expected Value of Recommendations
Versus Cost & Difficulty



“Postal Model” added as strategic alternative for Shelter in Place scenarios

“Home Medkits” could easily have been selected to “Top 8”